

need, age, or medical condition, and not based on current or former employment status.

(vi) Does not engage in midyear plan or noncalendar year plan enrollment changes on behalf of a substantial number of its members when authorized to do so on the beneficiary's behalf.

(2) *Use of a single card.* A card that is issued under § 423.120(c) for use under a Part D plan may also be used in connection with coverage of benefits provided under a SPAP and, in such a case, may contain an emblem or symbol indicating such connection.

(3) *Construction.* Nothing in this subpart requires a SPAP to coordinate with, or provide financial assistance to enrollees in, any Part D plan.

(f) *Coordination with other prescription drug coverage—(1) Definition of other prescription drug coverage.* Entities that provide other prescription drug coverage include any of the following:

(i) *Medicaid programs.* A State plan under title XIX of the Act, including such a plan operating under a waiver under section 1115 of the Act, if it meets the requirements of paragraph (e)(1)(ii) of this section.

(ii) Group health plans.

(iii) *FEHBP.* The Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code.

(iv) *Military coverage (including TRICARE).* Coverage under chapter 55 of title 10, United States Code.

(v) *Indian Health Service.* Coverage under Chapter 18 of title 28 of the United States Code.

(vi) *Federally qualified health centers.* Federally qualified health centers as defined under section 1861(aa)(4) of the Act.

(vii) *Rural health clinics.* Rural health clinics as defined under section 1861(aa)(2) of the Act.

(viii) Other Part D plans.

(ix) *Other prescription drug coverage.* Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of Part D drugs on behalf of Part D eligible individuals as CMS may specify.

(2) *Treatment under out-of-pocket rule.*

(i) For purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided

under § 423.104(d)(5)(iii), a Part D plan must do all of the following:

(A) Include the enrollee's incurred costs (as defined in § 423.100).

(B) Report, accept and apply benefit accumulator data in a timeframe and manner determined by CMS.

(C) Exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage.

(ii) A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

(3) *Imposition of fees.* A Part D sponsor may not impose fees on SPAPs and entities offering other prescription drug coverage that are unrelated to the cost of the coordination of benefits.

(4) *Authority to recover expenditures due to incorrect information on true out-of-pocket costs.* In the event that a Part D plan learns that it has made an erroneous payment due to inaccurate or incomplete information on the satisfaction of the out-of-pocket threshold under § 423.104(d)(5)(iii), that plan is authorized to recover such costs directly from the Part D enrollee on whose behalf the costs were incurred. A Part D enrollee must reimburse the Part D plan for payment made for these costs.

(5) *Plan-to-plan liability.* In the process of coordinating benefits between Part D plans when a Part D plan from which a beneficiary has transferred has incorrectly made payment for covered prescription drug costs incurred after the effective date of the Part D enrollee's enrollment in the new Part D plan of record, the new Part D plan of record must make the reconciling payments based on amounts reported to it by CMS without regard to the Part D plan's own formulary or drug utilization review edits.

(6) *Use of other reconciliation processes.* In the process of coordinating benefits between the correct Part D plan of record and another entity providing prescription drug coverage when that entity has incorrectly paid as primary payer for a covered Part D drug on behalf of a Part D enrollee, the correct Part D plan of record must achieve timely reconciliation through working

directly with the other entity that incorrectly paid as primary payer, unless CMS has established reconciliation processes for payment reconciliation, rather than requesting pharmacy claims reversal and re-adjudication.

(g) *Responsibility to account for other providers of prescription drug coverage when a retroactive claims adjustment creates an overpayment or underpayment.* When a Part D sponsor makes a retroactive claims adjustment, the sponsor has the responsibility to account for SPAPs and other entities providing prescription drug coverage in reconciling the claims adjustments that create overpayments or underpayments. In carrying out these reimbursements and recoveries, Part D sponsors must also account for payments made and for amounts being held for payment by other individuals or entities. Part D sponsors must have systems to track and report adjustment transactions and to support all of the following:

(1) Adjustments involving payments by other plans and programs providing prescription drug coverage have been made.

(2) Reimbursements for excess cost-sharing and premiums for low-income subsidy eligible individuals have been processed in accordance with the requirements in § 423.800(c).

(3) Recoveries of erroneous payments for enrollees as specified in § 423.464(f)(4) have been sought.

(h) *Reporting requirements.* A Part D sponsor must report credible new or changed supplemental prescription drug coverage information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 75 FR 19819, Apr. 15, 2010; 76 FR 21574, Apr. 15, 2011; 79 FR 29963, May 23, 2014; 80 FR 7964, Feb. 12, 2015]

§ 423.466 Timeframes for coordination of benefits and claims adjustments.

(a) *Retroactive claims adjustments, underpayment refunds, and overpayment recoveries.* Whenever a sponsor receives information that necessitates a retroactive claims adjustment, the sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the sponsor's receipt of com-

plete information regarding claims adjustment.

(b) *Coordination of benefits.* Part D sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period of 3 years from the date on which the prescription for a covered Part D drug was filled.

[75 FR 19819, Apr. 15, 2010, as amended at 80 FR 7964, Feb. 12, 2015]

Subpart K—Application Procedures and Contracts with Part D plan sponsors

§ 423.500 Scope.

This subpart sets forth application procedures and contracts with Part D plans: application procedures and requirements; contract terms; procedures for termination of contracts; reporting by Part D plans. For purposes of this subpart, Medicare Advantage (MA) organizations offering Part D plans follow the requirements of part 422 of this chapter for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements.

§ 423.501 Definitions

For purposes of this subpart, the following definitions apply:

Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the Part D plan sponsor's enrollees by pharmacies and other providers, by Part D plan sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Final settlement adjustment period means the period of time between when the contract terminates and the date the Part D sponsor is issued a notice of the final settlement amount.

Final settlement amount means the final payment amount that CMS owes and ultimately pays to a Part D sponsor, or that a Part D sponsor owes and ultimately pays to CMS, with respect to a Part D contract that has consolidated, nonrenewed, or terminated. The final settlement amount is calculated by summing final retroactive payment adjustments for a specific contract that accumulated after that contract ceases operation but before the calculation of the final settlement amount and all of the following applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating these reconciliation amounts:

(1) Risk adjustment reconciliation, as applicable (described in § 422.310 of this chapter).

(2) Part D annual reconciliation (described in § 423.343).

(3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320).

(4) MLR remittances (described in §§ 422.2470 of this chapter and 423.2470).

Final settlement process means for a contract that has been consolidated, nonrenewed, or terminated, the process by which CMS does all of the following:

(1) Calculates the final settlement amount.

(2) Issues the final settlement amount along with supporting documentation in the notice of final settlement to the Part D sponsor.

(3) Receives responses from the Part D sponsor requesting an appeal of the final settlement amount.

(4) Takes action to adjudicate an appeal (if requested) and make payments to or receive payments from the Part D sponsor. The final settlement amount is calculated after all applicable reconciliations have occurred after a contract has been consolidated, nonrenewed, or terminated.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Party in interest means the following:

(1) Any director, officer, partner, or employee responsible for management or administration of a Part D plan sponsor.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with the Part D plan sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

Prescription drug pricing standard means any methodology or formula for varying the pricing of a drug or drugs